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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,047	07/12/99	MULLER D	M-1492

HM12/0216

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EXAMINER	
SHAREH, S	
ART UNIT	**PAPER NUMBER**
1616	6

DATE MAILED: 02/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/214,047	Muller, Dieter
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *Jul 12, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-5* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The Preliminary Amendment, and the Disclosure Statement filed on December 23, 1998 have not been entered because it is unsigned.

Claim Objections

1. Claim 3 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1-2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "pharmaceutical administration form in form of an electromagnetic memory" is vague, because in the pharmaceutical art "a pharmaceutical administration form" is considered a dosage form that is administrable by any of the known routes of administration. In the instant case "an electromagnetic memory" considered as a pharmaceutical form is indefinite because it does not constitute a pharmaceutical form.

In claim 2, it is not clear how and what is characterized as a magnetic tape. Is that the electromagnetic memory stored in a magnetic tape? or is the magnetic tape the actual electromagnetic memory?

4. Claims 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps include: the preparation steps. It is not clear which steps are to be taken in order to prepare the claimed pharmaceutical form. Applicant is suggested to use the standard claim language such as; methods of preparing a pharmaceutical form comprising....

5. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear for treatment of what type of disease is the instant pharmaceutical form used for, or what type of steps are required to utilize the instant method of therapy.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using a bioresonance unit to create a magnetic

tape, does not reasonably provide enablement for methods of making or using a pharmaceutical administrable form for treating various disease states. Further, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

In particular, the specifications fails to enable the skilled artisan to practice the invention without undue experimentation. As held by *ex parte Forman* (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988) provide several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

The state of the prior art concerning methods of bioresonance therapy is controversial and speculative. In fact, the proponents of such alternative therapy believe that the physical science is the science of dead material and thus incapable of commenting on the effects of biological phenomena such as bioresonance therapy or other methods of acupuncture in treatments of various disease states. Furthermore, the pharmacological effects and benefits of such types of therapeutic approaches have not been described by scientific methodologies. Therefore, the specification does not provide adequate enablement for the claimed therapeutic utility of the instant invention.

However, it is known in the homeopathic art that in bioresonance therapy "the pathological electromagnetic wave patterns" which is different for specific disease state are corrected when converted to "normalized electromagnetic waves", using a specific analyzing

apparatus such as BIOCOM ™. Accordingly, the waves from one part of the body are taken up by a brass electrode, and analyzed in a separator of said apparatus. During this process, the pathological waves are separated from the normal (healthy) waves and then said pathological waves are reversed electronically by said separator and finally transmitted back to the patient by an exit electrode to produce its therapeutic effects (see Schoni et al, Int Arch Allergy Immunol.. 1997;12:238-246.) Hence, the bioenergy that is normalized during a treatment course of bioresonance therapy is actually generated within the body of the patient, and then corrected by an external apparatus. (see Schoni et al p.245, and specification p.5). Thus, there is no correlation between applying the bioresonance spectrum obtained of a medical compound (a dead entity) and its effects on a biological receptor system, because this approach is in contrary to the principles of the bioresonance theory. Further, there is no predictability in the art that said bioresonance spectrum obtained in the form of a magnetic tape can correct the pathological waves of a patient (as in accord with the bioresonance theory), neither is there any predictability in the mechanism of action of said spectrum on biological and cellular receptors. In addition, there is no prior knowledge in the art explaining the normal frequency of human's bioenergy, thus, one skilled in the art would not be able to determine the efficacy of such therapy without undue experimentation. Finally, the working examples do not provide any scientific guidance of how the instant pharmaceutical form exerts its pharmacologic benefits on the receptor system.

Moreover, the bioresonance therapy, as reported by Schoni et al, has revealed no therapeutic effects neither in the short- nor in the long-term management of specific skin allergy

or atopic dermatitis in children (see abstract.) The specification does not provide guidance as to how one skilled in the art would go about treating a specific diseases within the scope of the presently claimed invention. Nor is any guidance provided to a specific protocol that can be utilized in order to prove the efficacy of the presently claimed pharmaceutical form in treating the claimed disease states. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention. Thus, the specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with the instant claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Berner et al DE 3419055.

The instant claim is directed to a pharmaceutically administrable form comprising a bioresonance spectrum of a medical compound.

Brenner disclose a magnetic foil sheet for biophysical therapy comprising plastic matrix and magnetic particles (see abstract.) Therefore, Brenner meets the limitations set forth in the instant claim.

10. Claims 1-3, 5 rejected under 35 U.S.C. 102(b) as being anticipated by Whitson-Fischman US Patent 5,162,037.

The instant claims are directed to a pharmaceutically administration form comprising bioresonance spectrum of a medical compound in a magnetic tape, and methods of using said administration form in treatment of various disease states.

Whitson-Fischmann disclose methods of impregnating a topical patch comprising a homeopathic medicament and a magnetically permeable ingredient that is magnetized (see abstract, col 6 lines 35-68, col 7 lines 1-30) Whitson-Fischmann further disclose methods of using his patch by aligning it near a selected acupuncture point on the patient's skin (see col 9 lines 29-61, col 40 lines 16-40.) Thus, Whitson-Fischmann meets the limitations set forth in the instant claims.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

11. Claims 1, 4-5 rejected under 35 U.S.C. 102(e) as being anticipated by Dillinger et al US Patent 5,830,140

The instant claims are directed to a pharmaceutically administration form comprising bioresonance spectrum of a medical compound in a magnetic tape, and methods of using said administration form in treatment of various disease states.

Dillinger et al teach the use of a bioresonance apparatus to register the substance specific or body specific energetic information in the form of electromagnetic spectra to produce a

homeopathic medicament composition (see col 1 lines 1-65, col 3 lines 40-67, col 4 lines 65-67.) Therefore, Dillinger et al meet the limitaions set forth in the isntant claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dillinger et al US Patent 5,830,140 in view Whitson-Fischmann US Patent 5,162,037.

The instant claims are directed to a pharmaceutically administration form comprising bioresonance spectrum of a medical compound in a magnetic tape, and methods of preparing and using said administration form.

Whitson-Fischmann's teachings are described above.

Dillinger et al teach the use of a bioresonance apparatus to register the substance specific or body specific energetic information in the form of electromagnetic spectra to produce a homeopathic medicament composition (see col 1 lines 1-65, col 3 lines 40-67, col 4 lines 65-67.)

Although Dillinger et al do not teach methods of applying a topical tape containing the electromagnetic spectra of a pharmaceutical compound on a acupuncture points of patients, they teach the use of their method for preparing a homeopathic medicament composition, therefore, in order to enhance the internal energy flow of those patients who are suffering from a pathological

condition that is caused by altered electromagnetic bioenergy, one ordinary skilled in the art would have had a reasonable expectation to succeed in applying an electromagnetic spectrum of a therapeutic agent of choice in the form of a topical medicament to the acupuncture points of patients because as taught by Whitson-Fischmann the application of a magnetic energy to the acupuncture points is well known in the art.

Conclusion

No claims were allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs, 2/3/2000

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616